Supreme Court, U.S.
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No. 09-335

In The Supreme Court of the United States

ASTELLAS PHARMA, INC.,

Petitioner,

v.

LUPIN LIMITED, ET AL.,

Respondents.

On Petition for Writ of Certiorari to the United States Court of Appeals for the Federal Circuit

BRIEF IN OPPOSITION

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QUESTION PRESENTED

Whether the United States Court of Appeals for the Federal Circuit's *en banc* decision, which resolved an intra-circuit split in a manner consistent with this Court's precedent, properly found that claims reciting a product made by a certain process are not infringed by a product made by a different process?

PARTIES TO THE PROCEEDING AND CORPORATE DISCLOSURE STATEMENT

The parties to the proceedings are: Petitioner/Appellant Astellas Pharma, Inc. and Respondents/Appellees Lupin Ltd., Lupin Pharmaceuticals, Inc., Sandoz Inc., Sandoz GmbH, Teva Pharmaceuticals USA, Inc., Teva Pharmaceutical Industries, Ltd., Ranbaxy, Inc., Par Pharmaceutical Companies, Inc. and Par Pharmaceutical. Abbott Laboratories was an appellant below, but has not joined in the petition for *certiorari*.

As required by the Court's Rule 29.6:

Teva Pharmaceuticals USA, Inc. states that it is a wholly-owned subsidiary of Teva Pharmaceutical Industries, Ltd.

Teva Pharmaceutical Industries, Ltd. states that there is no parent corporation and no publicly held company that owns 10% or more of its stock.

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STATEMENT OF THE CASE

This is a patent litigation that involves a rarely-employed patent claim format known as a "product-by-process" claim. A "product-by-process" claim is a patent claim that recites a product made by a certain process. The issue presented in the petition is whether, in determining infringement of a product-by-process claim, the process terms recited in the claim serve as limitations, or whether the process terms must be ignored.

The Federal Circuit's *en banc* decision, *Abbott Labs. v. Sandoz, Inc.*, 566 F.3d 1282 (Fed. Cir. 2009) (*en banc* in part) (App. 1), held that the process terms in product-by-process claims serve as limitations in determining infringement.

The facts of the case are set forth in the Federal Circuit's *en banc* decision below, and will not be repeated here.

REASONS WHY THE PETITION SHOULD BE DENIED

The petition for certiorari should be denied because the *en banc* decision below resolves any existing conflicts on an issue of patent law that arises only rarely. Moreover, the issue was correctly decided in accordance with this Court's precedent.

Petitioner argues that the Federal Circuit decision was wrong, relying on the arguments from the dissent below that eight of the eleven circuit judges sitting *en banc* found unconvincing. Petitioner fails to identify any issue or doctrinal conflict worthy of certiorari.

I. Certiorari Is Not Appropriate For A Narrow Decision On A Rarely-Arising Issue

Although the Court can, of course, grant certiorari to address important issues of Federal law, this is not such a case. The narrow issue of patent law addressed in this case is "whether [a product-by-process] claim is infringed by products made by processes other than the one claimed." App. 23. Courts rarely are forced to confront such an infringement analysis. Indeed, prior to the Federal Circuit's *en banc* decision below, the issue apparently had arisen only on two previous occasions in the twenty-five year history of the Court of Appeals for the Federal Circuit. *See Scripps Clinic & Research Found. v. Genentech, Inc.*, 927 F.2d 1565 (Fed. Cir. 1991) (*overruled* by *Abbott*); *Atlantic Thermoplastics Co. v. Faytex Corp.*, 970 F.2d 834 (Fed. Cir. 1992). In the seventeen years between *Atlantic Thermoplastics* and the *en banc* decision, only one other of the thousands of reported opinions issued by the Federal Circuit appears to have even indirectly ruled on the issue of infringement of a product-by-process claim.[1] The paucity of cases affected by the *en banc* decision underscores the rarity of this issue because the Federal Circuit heard all appeals in cases arising under the patent laws since its formation in 1982.

Petitioner alleges, without citation, that the decision below affects "thousands of active patent

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[1] *See Monsanto Co. v. Syngenta Seeds, Inc.*, 503 F.3d 1352 (Fed. Cir. 2007) (ruling that if a particular dependent patent claim were construed as a product-by-process claim, the process steps of the base claim would be considered limitations in an infringement analysis).

claims." Pet. Br. 2. According to Petitioner, "product-by-process claims are more important now than they have ever been . . . in the areas of pharmaceuticals and biotechnology . . . ." Pet. Br. 29-30. Yet, not a single amicus filed a brief in support of Petitioner. Even Petitioner's co-appellant below, Abbott Laboratories – a noted pharmaceutical and biotechnology company with a direct stake in the outcome of this litigation – declined to join the petition for certiorari. Pet. Br. ii.

II. There Is No Doctrinal Conflict Worthy Of Certiorari

The Federal Circuit's *en banc* decision clarifies its prior *Scripps* and *Atlantic Thermoplastic* decisions, in keeping with this Court's precedent. The decision gives meaning to all of the words of a patent claim when determining infringement, including the recited process terms of product-by-process claims. *See Warner-Jenkinson Co. v. Hilton Davis Chem. Co.*, 520 U.S. 17, 29 (1997).

Petitioner identifies three of this Court's decisions that it asserts conflict with the Federal Circuit's *en banc* decision: *Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*, 489 U.S. 141 (1989), *Peters v. Active Mfg. Co.*, 129 U.S. 530 (1889) and *White v. Dunbar*, 119 U.S. 47 (1886). *See* Pet. Br. 11-15, 16-17, 20-21. However, none of those cases set out or require a rule contrary to that announced in the decision below.

Petitioner also argues that certiorari is appropriate due to purported procedural irregularities in the Federal Circuit's decision to take the issue *en banc*. Petitioner's procedural arguments are a red herring, since the Federal Circuit acted within its operating

procedures to resolve the issues efficiently, and because additional briefing would have served no purpose.

Finally, Petitioner argues that the Federal Circuit's *en banc* decision conflicts with prior decisions of the Federal Circuit and other lower courts.[2] Even if that were so, it could not serve as a proper basis for certiorari since the Federal Circuit's *en banc* decision would settle any such prior conflict. Certiorari is rarely, if ever, granted to overturn an *en banc* decision which clarifies intra-circuit precedent. *See* E. Gressman, Supreme Court Practice, 253-54 (BNA Books 9th ed. 2007).

A. The Federal Circuit's *En Banc* Decision Is Correct, And Follows This Court's Precedent

The Federal Circuit's *en banc* decision holds that the recited process steps in product-by-process claims cannot be ignored, and serve to limit the scope of any claim for infringement. App. 26. This rule is well-settled and consistent with this Court's precedent.

First, this rule for the infringement of product-by-process claims squares precisely with this Court's general pronouncement that "[e]ach element contained

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[2] For example, Petitioner argues that the decision below improperly rewrites the claim language of claims 2-5 of the patent in suit. Pet. Br. 27-29. In essence, Petitioner argues that the claims should be interpreted as something other than product-by-process claims. This issue is irrelevant because it is outside the scope of the question Petitioner seeks to present to this Court. *See* Pet. Br. i.

in a patent claim is deemed material to defining the scope of the patented invention." *Warner-Jenkinson*, 520 U.S. at 29.

Second, this rule is also consistent with this Court's precedent on product-by-process claims in particular. For example, in *BASF*, when considering the infringement of a product-by-process claim in 1884, this Court stated:

> Every patent for a product or composition of matter must identify it so that it can be recognized aside from the description of the process for making it, or else nothing can be held to infringe the patent which is not made by that process.

Cochrane v. Badische Anilin & Soda Fabrik, 111 U.S. 293, 310 (1884) ("*BASF*"). The Court concluded that "[u]nless that process will practically produce the defendant's article . . . [the patent-in-suit] is not infringed." *Id.* at 311.

The Federal Circuit's *en banc* decision correctly notes that other decisions of this Court also give meaning to the process that is recited in a product-by-process patent claim. App. 18-19. *See, e.g., Smith v. Goodyear Dental Vulcanite Co.*, 93 U.S. 486, 493 (1876); *Goodyear Dental Vulcanite Co. v. Davis*, 102 U.S. 222, 224 (1880); *The Wood-Paper Patent*, 90 U.S. 566, 596 (1874); *Plummer v. Sargent*, 120 U.S. 442, 448-450 (1887); *Gen. Elec. Co. v. Wabash Appliance Corp.*, 304 U.S. 364, 373-74 (1938).

The Federal Circuit rule also follows a long line of other circuit courts which reached the same conclusion as *BASF*:

> It is also a well-recognized rule that, although a product has definite characteristics by which it may be identified apart from the process, still, if in a claim for the product it is not so described, but is set forth in the terms of the process, nothing can be held to infringe the claim which is not made by the process.

Hide-Ite Leather Co. v. Fiber Prods. Co., 226 F. 34, 36 (1st Cir. 1915) (citing *BASF*, 111 U.S. at 312); *accord Downes v. Teter-Heany Development Co.*, 150 F. 122, 124 (3d Cir. 1907), *cert. denied*, 205 U.S. 543 (1907); *see also Buono v. Yankee Maid Dress Corp.*, 77 F.2d 274, 279 (2d Cir. 1935) (L. Hand, J.) (claims to a product of a machine or a process "would in that case not be infringed by anything but the product of the machine or of the process . . .").

1. *Bonito Boats* Confirms That Product-By-Process Claims Are Infringed By Products Made By The Recited Process

Petitioner argues that the Federal Circuit decision conflicts with this Court's decision in *Bonito Boats*. Pet. Br. 16-17, 20-21. Petitioner misreads that decision. *Bonito Boats* addressed the constitutionality of a Florida statute that prohibited using a particular method of making boat hulls and sale of the resulting boat hulls. The statute, which the Court said "resembles that of a so-called 'product-by-process' patent," was preempted by the patent laws since it granted boat hull manufacturers substantial control

over "the use of a particular process and the ***sale of an article created by that process*** . . . ." *Bonito Boats*, 489 U.S. at 158, n* (emphasis added). The Court stated:

> The statute makes "[i]t . . . unlawful for any person to use the direct molding process to duplicate for the purpose of sale any manufactured vessel hull or component part of a vessel made by another without the written permission of that other person." § 559.94(2). The statute also makes it unlawful for a person to "knowingly sell a vessel hull or component part of a vessel duplicated in violation of subsection (2)." § 559.94(3).

Id. at 144-5. Thus, the Court likened product-by-process patent claims to a statute that covered a product (vessel hulls) made by a particular process (direct molding). Since the statute was violated only when the specific process was used, the Federal Circuit's decision below is fully consistent with the discussion of product-by-process claims in *Bonito Boats*.

Petitioner argues that *Bonito Boats* somehow supports a rule that a product-by-process claim should be interpreted to ignore the recited process if the product is found to be new, but require the recited process if the product is old. Pet. Br. 16-17, 20-21. Petitioner relies on a single statement, in a footnote, that "a patent in the process may support a patent in the resulting product" if "the end product of the process is adequately defined and novel and nonobvious." *Bonito Boats*, 489 U.S. at 158, n*. The footnote says nothing about how product-by-process

patent claims should be interpreted for infringement or validity, and cannot be said to set forth a new rule with respect to "new" or "old" products. In short, *Bonito Boats* agrees that a product-by-process claim "'is one in which the product is defined at least in part in terms of the method or process by which it is made.'" *Id.* (quoting D. Chisum, Patents, § 8.05, p. 8-67 (1988)).

2. The Limited Infringement Holding In This Case Does Not Conflict With This Court's Precedent Relating To Validity

Unable to demonstrate that the Federal Circuit's decision below directly conflicts with prior precedent of this Court, or even of sister circuits from the days before the creation of the Federal Circuit, Petitioner contends that the Federal Circuit's *en banc* decision conflicts with this Court's decision in *Peters*, which reasons "[t]hat which infringes, if later, would anticipate, if earlier." Pet. Br. 12 (quoting *Peters*, 129 U.S. at 537 (1889)); *see also White*, 119 U.S. at 51 (a claim is not "a nose of wax which may be turned and twisted in any direction"). Petitioner argues that, under the rule of *Abbott*, "claims are now interpreted differently for validity purposes than for infringement purposes." Pet. Br. 11.

Petitioner's attempt to broaden the ruling of the decision below in order to find a conflict with precedent is unavailing. First and foremost, the *en banc* decision below neither states nor implies that the infringement rule creates any different interpretation of patent claims for validity analyses. The *en banc* decision below, and the district court decisions that it reviewed, were directed only to the issue of infringement, and

did not address validity. App. 23 ("The issue here is only whether such a claim is infringed by products made by processes other than the one claimed. This court holds that it is not."). Only infringement issues were considered and discussed below – not validity. This Court should decline Petitioner's invitation to disturb an infringement holding that follows this Court's overwhelming precedent, and should not address validity issues that go beyond the bounds of the narrow decision below.

Second, Petitioner relies on the Federal Circuit panel decision in *Atlantic Thermoplastics* to argue there is a conflict. Pet. Br. 13. However, *Atlantic Thermoplastics* rejected the notion that patent claims are interpreted differently for patent validity and infringement. Indeed, *Atlantic Thermoplastics* unambiguously stated:

> In any event, claims mean the same for infringement and validity.

Atlantic Thermoplastics, 970 F.2d at 846. The *Atlantic Thermoplastics* court explained that patentability and validity are two separate and distinct concepts: patentability is the administrative standard used by the Patent Office ("PTO") to determine whether to issue a patent, whereas validity is the standard used by courts to revoke issued patent claims.[3] *Id.* "Thus, accommodating the demands of the administrative

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[3] The difference between the administrative patentability standard used by the PTO and the validity standard used by courts is well recognized for all patent claim formats, not just product-by-process claims. *See, e.g., In re Zletz*, 893 F.2d 319, 321 (Fed. Cir. 1989).

process and recognizing the capabilities of the trial courts, ***this court treats claims differently for patentability as opposed to validity and infringement***." *Id.* (emphasis added).[4]

Subsequent to the *Abbott* decision, a Federal Circuit panel noted a dichotomy between the interpretation of product-by-process claims for infringement and for validity. *See Amgen Inc. v. F. Hoffmann-LaRoche Ltd.*, 580 F.3d 1340 (Fed. Cir. Sept. 15, 2009).[5] To the extent that the *Amgen* panel decision conflicts with the prior panel opinion in *Atlantic Thermoplastics*, this petition is not the proper vehicle for resolving that tension. Any intra-circuit divergence should be addressed first *en banc* by the Federal Circuit. The present petition for certiorari, of a case that does not address validity in any manner, fails to warrant certiorari.

B. The *En Banc* Decision Below Clarified Intra-Circuit Authority And Does Not Warrant Certiorari

"[I]t is primarily the task of a Court of Appeals to reconcile its internal difficulties." *Wisniewski v.*

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[4] Petitioner also relies on Judge Newman's dissent to the *en banc* decision, which states, without support, that for validity, such claims are "independent of how the products can be made." App. 82. This bare statement cannot create a conflict in the face of the clear statement in *Atlantic Thermoplastics* that "claims mean the same for infringement and validity." *Atlantic Thermoplastics*, 970 F.2d at 846.

[5] None of the eight members of the *Abbott en banc* majority were on the *Amgen* panel.

United States, 353 U.S. 901, 902 (1957). The *en banc* decision below clarified prior panel decisions within the Federal Circuit on the proper interpretation of product-by-process claims for infringement. Review of such *en banc* decisions by the Supreme Court is disfavored. *See* E. Gressman, Supreme Court Practice, 253-54 (citing *Davis v. United States*, 417 U.S. 333, 340 (1974)); J. Moore, Moore's Federal Practice, § 510.21[2], p. 510–15 (3d ed. 2009).

C. The Federal Circuit Followed Appropriate Procedure

Petitioner argues that the Federal Circuit's *sua sponte* decision to take the appeal *en banc* is grounds for grant of certiorari because the Federal Circuit's internal operating procedures provide for notice and opportunity for amicus briefing when proceeding *en banc*. However, as Petitioner is forced to concede, "[the Federal Circuit's] internal operating procedures state that the Federal Circuit is not bound by those procedures." Pet. Br. 9; *see also* United States Court of Appeals for the Federal Circuit, Internal Operating Procedures Rule 1.1[6] ("The court reserves the right to depart from a provision in the IOPs when circumstances require.").

In this instance, the Federal Circuit sought to clarify intra-circuit precedent and plainly saw no utility in seeking additional briefing, or amicus briefs, on this limited issue. Far from acting in a manner which would raise any eyebrows, the Federal Circuit acted commendably to resolve the issue efficiently. In

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[6] Available at http://www.cafc.uscourts.gov/pdf/IOPs122006.pdf.

sharp contrast, Petitioner's claims that they were unfairly denied additional briefing ring hollow where: (1) the petition simply reiterates arguments Judge Newman raised in dissent to the *en banc* panel, (2) no amici filed in support of the petition for certiorari, and (3) Abbott itself, a co-plaintiff below, has abandoned further appeals. In any event, the Federal Circuit's actions in proceeding *en banc* were within the scope of its operating procedures, and cannot form the basis for grant of certiorari.

CONCLUSION

For these reasons, the petition for a writ of certiorari should be denied.

Respectfully submitted,

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